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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HELLING, KAITLYN ELIZABETH

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PAPER NUMBER

3739

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12/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,391	Applicant(s) BOOTH ET AL.	
	Examiner KAITLYN E. HELLING	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-14 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-14 and 16-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/23/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 2, 4-9, 13, 14, 16-22 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 5,620,481 to Desai et al. (Desai) in view of U.S. 5,892,667 to Glasband et al. (Glasband).

Desai teaches a device for multi-phase radio-frequency ablation (title) which includes a two-dimensional or three-dimensional electrode array (Abstract), an indifferent electrode, in the form of a backplate (40, Fig. 14b), and a plurality of phase shifting circuits, such as RC or RL pairs that have substantially the same amplitude, but their phases have been shifted relative to each other. However, Desai does not teach a transformer having a primary winding, a secondary winding and a ferrite core, the secondary winding having at least one tap to provide a ground reference and at least two sources of energy or that the indifferent electrode is connected to the ground reference of the tap with the ground reference of the tap and the indifferent electrode being tied to a ground reference on the primary side of the transformer. Glasband teaches a symmetrical power system with a transformer (12, Fig. 1 and Abstract) having a primary (14, Fig. 1 and Col. 5, lines 47-48) and secondary winding (16 and 18, Fig. 1 and Col. 5, line 48-50), the secondary winding having a center tap (20, Fig. 1) which is connected to ground (30, Fig. 1 and Col. 5, lines 56-57), two sources for supplying energy (Fig. 1) and the energy output at the ends of the two sources being out of phase

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with on another (Col. 5, lines 65-66). Glasband, however, does not teach the use of a ferrite core. It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the plurality phase shifting circuits of Desai with the transformer of Glasband as the transformer would be an alternate equivalent to the plurality phase shifting circuits of Desai. This is particularly true as Glasband teaches that the symmetrical power supply is uniquely configured and referenced to operate sensitive electronics, i.e. electrodes, and other impedance loads, i.e. the body, in a manner that inhibits propagation of most interference.

Regarding the use of a ferrite core, as ferrite is a known ferromagnetic material with a high initial permeability and is commonly used in radio frequency device, it would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the core of Glasband with a ferrite core, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

With regards to the indifferent electrode is connected to the ground reference of the tap with the ground reference of the tap and the indifferent electrode being tied to a ground reference on the primary side of the transformer, the examiner asserts that in light of the lack of any disclosed criticality for the specific arrangement of the connection of the ground reference to the tap and the indifferent electrode being connected to a ground reference on the primary side of the transformer, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified

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Glasband and Desai as it has been held that the mere rearrangement of parts is not patentably significant if it does not impact the operation of the device.

Regarding claim 2, Desai and Glasband teach the system of claim 1 with Glasband teaching the primary winding being connected to an output of an energy generator (Fig. 1). However, Glasband does not teach the energy generator supplying radio frequency energy. Desai teaches the further limitation of the inclusion of a radio frequency energy generator (220, Fig. 2a and Col. 6, lines 61-62). The coupling of the primary winding of the transformer to the output of the energy generator will inherently flow from the combination of Desai and Glasband as the energy must first flow through the phase shifting circuits.

Regarding claim 4, Desai and Glasband Desai teach the system of claim 1, with Glasband teaching that any desired voltage can be achieved by the appropriate selection of the ratio of output to input turns of a transformer (Col. 6, lines 29-31). The examiner asserts that it would, therefore, have been obvious to one having ordinary skill in the art at the time of the invention to have used a transformer with a 1:1 ratio between the primary and secondary windings if that ratio provided the desired outcome (See MPEP 2144.05).

Regarding claim 5, Desai and Glasband teach the system of claim 1 with Glasband teaching the further limitation of the center tap providing two sub-windings (16 and 18, Fig. 1) which act as energy sources (Col. 5, lines 60-64) with the energy supplied being 180° out of phase with respect to each other (Col. 5, lines 65-66). The particular parameters of the transformer will necessarily be a part of the combination of

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Desai and Glasband as the transformer of Glasband is being substituted for the plurality of phase shifting circuits of Desai.

Regarding claims 6 and 7, Desai and Glasband teach the system of claim 5 with Desai teaching the further limitation of the electrodes attached to the free end of each sub-winding with the electrodes arranged in groups relative to the site being treated (Fig. 8 and Col. 9, lines 41-50). It would have been obvious to one having ordinary skill in the art at the time of the invention to have included the further limitation of the electrodes attached to the sub-windings and arranged in groups relative to the site being treated of Desai since Desai teaches that this is the preferred electrode array and that by the judicious pairing of the electrodes, a two-phase radio frequency supply is able to produce a fairly uniform lesion (Col. 9, lines 12-21).

Regarding claim 8, Desai and Glasband teach the system of claim 6, with Desai teaching to provide more than two connections to the radio frequency energy generator (Fig. 2a and Col. 6, lines 48-62). Therefore, the examiner asserts that it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Desai and Glasband to have included intermediate taps between the ground reference tap and the free end of each sub-winding to provide more than two sub-windings acting as energy sources since the mere duplication of parts has no patentable significance unless a new and unexpected result is produced (See MPEP 2144.04).

Regarding claim 9, Glasband and Desai teach the system of claim 1, with Desai teaching the electrode assembly comprising a co-axially arranged pair of electrodes

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which are displaceably arranged relative to each other (Figs. 8a, 8b and Col. 9, line 41 – Col. 10, line 3).

Regarding claim 13, Desai teaches a method of heating a biological site including a device for multi-phase radio-frequency ablation (title) which includes a two-dimensional or three-dimensional electrode array (Abstract), an indifferent electrode, in the form of a backplate (40, Fig. 14b), and a plurality of phase shifting circuits, such as RC or RL pairs that have substantially the same amplitude, but their phases have been shifted relative to each other. However, Desai does not teach a transformer having a primary winding, a secondary winding and a ferrite core, the secondary winding having at least one tap to provide a ground reference and at least two sources of energy or that the indifferent electrode is connected to the ground reference of the tap with the ground reference of the tap and the indifferent electrode being tied to a ground reference on the primary side of the transformer. Glasband teaches a symmetrical power system with a transformer (12, Fig. 1 and Abstract) having a primary (14, Fig. 1 and Col. 5, lines 47-48) and secondary winding (16 and 18, Fig. 1 and Col. 5, line 48-50), the secondary winding having a center tap (20, Fig. 1) which is connected to ground (30, Fig. 1 and Col. 5, lines 56-57), two sources for supplying energy (Fig. 1) and the energy output at the ends of the two sources being out of phase with on another (Col. 5, lines 65-66). Glasband, however, does not teach the use of a ferrite core. It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the plurality phase shifting circuits of Desai with the transformer of Glasband as the transformer would be an alternate equivalent to the plurality phase shifting

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circuits of Desai. This is particularly true as Glasband teaches that the symmetrical power supply is uniquely configured and referenced to operate sensitive electronics, i.e. electrodes, and other impedance loads, i.e. the body, in a manner that inhibits propagation of most interference.

Regarding the use of a ferrite core, as ferrite is a known ferromagnetic material with a high initial permeability and is commonly used in radio frequency device, it would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the core of Glasband with a ferrite core, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

With regards to the indifferent electrode is connected to the ground reference of the tap with the ground reference of the tap and the indifferent electrode being tied to a ground reference on the primary side of the transformer, the examiner asserts that in light of the lack of any disclosed criticality for the specific arrangement of the connection of the ground reference to the tap and the indifferent electrode being connected to a ground reference on the primary side of the transformer, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified

Regarding claim 14, Desai and Glasband teach the system of claim 13 with Glasband teaching the primary winding being connected to an output of an energy generator (Fig. 1). However, Glasband does not teach the energy generator supplying radio frequency energy. Desai teaches the further limitation of the inclusion of a radio frequency energy generator (220, Fig. 2a and Col. 6, lines 61-62). The coupling of the

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primary winding of the transformer to the output of the energy generator will inherently flow from the combination of Desai and Glasband as the energy must first flow through the phase shifting circuits.

Regarding claim 16, Desai and Glasband teach the method of claim 13, with Glasband teaching that the selection of a desired voltage can be achieved by the appropriate selection of the ratio of output to input turns of a transformer (Col. 6, lines 29-31). The examiner asserts that it would, therefore, have been obvious to one having ordinary skill in the art at the time of the invention to have used a transformer with a 1:1 ratio between the primary and secondary windings if that ratio provided the desired outcome (See MPEP 2144.05).

Regarding claim 17, Desai and Glasband teach the system of claim 13 with Glasband teaching the further limitation of the center tap providing two sub-windings (16 and 18, Fig. 1) which act as energy sources (Col. 5, lines 60-64) with the energy supplied being 180° out of phase with respect to each other (Col. 5, lines 65-66). The particular parameters of the transformer will necessarily be a part of the combination of Desai and Glasband as the transformer of Glasband is being substituted for the plurality of phase shifting circuits of Desai.

Regarding claims 18 and 19, Desai and Glasband teach the method of claim 17 with Desai teaching the further limitation of connecting the electrodes to the free end of each sub-winding with the electrodes arranged in groups relative to the site being treated (Fig. 8 and Col. 9, lines 41-50). It would have been obvious to one having ordinary skill in the art at the time of the invention to have included the further limitation

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of the electrodes attached to the sub-windings and arranged in groups relative to the site being treated of Desai since Desai teaches that this is the preferred electrode array and that by the judicious pairing of the electrodes, a two-phase radio frequency supply is able to produce a fairly uniform lesion (Col. 9, lines 12-21).

Regarding claim 20, Desai and Glasband teach the method of claim 18, with Desai teaching to form more than two connections to the radio frequency energy generator (Fig. 2a and Col. 6, lines 48-62). Therefore, the examiner asserts that it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Desai and Glasband to have included intermediate taps between the ground reference tap and the free end of each sub-winding to provide more than two sub-windings acting as energy sources since the mere duplication of parts has no patentable significance unless a new and unexpected results is produced (See MPEP 2144.04).

Regarding claim 21, Desai and Glasband teach the method of claim 18, with Desai teach the further limitation of the electrode being placed transmurally at a site (Col. 1, line 60 – Col. 2, line 10).

Regarding claim 22, Desai and Glasband teach the method of claim 18, with Desai teaching arranging of the electrode assembly as a co-axially arranged pair of electrodes which are displaceably arranged relative to each other (Figs. 8a, 8b and Col. 9, line 41 – Col. 10, line 3).

3. Claims 10-12 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 5,892,667 to Glasband et al. and U.S. 5,620,481 to Desai et al.

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as applied to claims 9 and 22 above, and further in view of U.S. 6,497,704 B2 to Ein-Gal (Ein-Gal).

Regarding claim 10, Desai and Glasband teach the system of claim 9, but not at least one of the electrodes having a helical tip. Ein-Gal teaches an electrosurgical apparatus (title) which includes an electrode with a helical tip for screwing the electrode into the site (Col. 5, lines 48-53 and Col. 6, lines 12-17). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Desai and Glasband with the helical tip of Ein-Gal as Ein-Gal teaches that it is preferable to be able to screw the electrode into a tissue (Col. 6, lines 12-17).

Regarding claim 11, Desai, Glasband and Ein-Gal teach the system of claim 10, with Ein-Gal teaching the further limitation of both electrodes of the assembly being helically tipped to be screwed into the site (Figs. 6A, 6B and Col. 10, lines 18-40). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Desai, Glasband and Ein-Gal to have included the further limitation of both electrodes being helically tipped as Ein-Gal teaches that it is advantageous to be able to screw the electrode into a tissue (Col. 6, lines 12-17).

Regarding claim 12, Desai, Glasband and Ein-Gal teach the system of claim 11, with Ein-Gal teaching the further limitation of the helical-tipped electrodes being of different pitches (Col. 6, lines 18-22). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Desai, Glasband and Ein-Gal with the further limitation of the helical-tipped electrodes being of different pitches since Ein-Gal teaches that the longitudinal direction of the lesion is basically

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dependent on the length of the electrode that is inserted into the tissue (Col. 1, lines 29-42).

Regarding claim 23, Desai and Glasband teach the method of claim 22, but not providing that at least one of the electrodes having a helical tip. Ein-Gal teaches an electrosurgical apparatus (title) which includes an electrode with a helical tip for screwing the electrode into the site (Col. 5, lines 48-53 and Col. 6, lines 12-17). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Desai and Glasband with the helical tip of Ein-Gal as Ein-Gal teaches that it is preferable to be able to screw the electrode into a tissue (Col. 6, lines 12-17).

Regarding claim 24, Desai, Glasband and Ein-Gal teach the method of claim 23, with Ein-Gal teaching the further limitation of both electrodes of the assembly being helically tipped to be screwed into the site (Figs. 6A, 6B and Col. 10, lines 18-40) and the helical-tipped electrodes being of different pitches (Col. 6, lines 18-22). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Desai, Glasband and Ein-Gal to have included the further limitation of both electrodes being helically tipped and of different pitches as Ein-Gal teaches that it is advantageous to be able to screw the electrode into a tissue (Col. 6, lines 12-17) and that the longitudinal direction of the lesion is basically dependent on the length of the electrode that is inserted into the tissue (Col. 1, lines 29-42).

Response to Arguments

4. Applicant's arguments, see Remarks page 8, filed October 23, 2009, with respect to now cancelled claim 28 whose subject matter has been included in amended claims

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1 and 13 have been fully considered and are persuasive. The rejection under 35 U.S.C. 112, first paragraph of June 23, 2009 has been withdrawn.

5. Applicant's arguments filed October 23, 2009 have been fully considered but they are not persuasive.

With respect to applicant's argument that Glasband does not teach, describe or disclose the power system being used with unbalanced loads, the examiner would point out that Glasband need not teach unbalanced loads. Glasband is being relied upon to teach the required transformer as an alternative equivalent to the plurality of phase shifting circuits of Desai. Desai teaches the load and the use of a reference backplate.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAITLYN E. HELLING whose telephone number is (571)270-5845. The examiner can normally be reached on Monday - Friday 9:00 a.m. to 5:30 p.m. EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571)272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. E. H./
Examiner, Art Unit 3739

/Roy D. Gibson/
Primary Examiner, Art Unit 3739